ANDA 74-827

READING FILE

21 1997

Lemmon Company
Attention: Deborah A. Jaskot
650 Cathill Road
Sellersville, PA 18960

Dear Madam:

This is in reference to your abbreviated new drug application dated December 27, 1995, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Captopril and Hydrochlorothiazide Tablets USP, 25mg/15mg, 50mg/15mg, 25mg/25mg, and 50mg/25mg.

Reference is also made to your amendments dated October 9, 1996; and May 23, June 23, and July 7, 1997.

We have completed the review of this abbreviated application and have concluded that based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is **tentatively approved**. This determination is contingent upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product), and is therefore subject to change on the basis of new information that may come to our attention. The listed reference drug upon which you have based your application is subject to a period of patent protection; therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(4)(B) of the Act until the period has expired, i.e., December 27, 1997.

Please provide the Agency, at least 60 days prior to December 27, 1997, an amendment to this application. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as labeling, chemistry, manufacturing, and controls data as appropriate. An amendment should also be submitted even if none of these changes were made. This submission should be designated as a MINOR AMENDMENT in your cover letter. In addition to, or instead of, the amendment requested above, the Agency may, at any time prior to the final date of approval, request that you submit an amendment containing the information described above. Failure to submit such an amendment requested by the Agency will prompt a review of the application which may result in rescission of this tentative approval letter.

Any significant changes in the conditions outlined in this abbreviated application require Agency approval before the changes may be made effective.

Prior to issuance of a final approval letter by the Agency, your product will not be deemed approved for marketing under 21 U.S.C. 355 and will not be listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list (the Orange Book), published by the Agency. Should you believe that there are grounds for our issuance of a final approval letter prior to December 27, 1997, you should amend your application accordingly.

At the time you submit any amendments, you should contact Mr. James Wilson, Project Management Officer, at (301) 827-5848, for further instructions.

The introduction or delivery for introduction into interstate commerce of the drug product before the effective approval date is prohibited under 21 U.S.C. 331(d).

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research